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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,418	07/11/2003	Daniel R. Deakter		7063

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Daniel R. Deakter
8281 Hampton Wood Drive
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EXAMINER

PORTER, RACHEL L

ART UNIT	PAPER NUMBER
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3626

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,418	Applicant(s) DEAKTER, DANIEL R.	
	Examiner RACHEL L. PORTER	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 7/11/03. Claims 1-17 are pending.

Information Disclosure Statement

2. The IDS's filed 7/11/2003, 3/9/2004, and 1/14/2005 have been entered and considered by the Examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 8-10, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, **System makes it easier to link patients to clinical trials** (hereinafter Baldwin) in view of Angiogenesis Weekly, **Clinical Trials; Comprehensive Online Resource Launched** (hereinafter Veritas).

As per claim 1, Baldwin discloses a system for enrolling patients in a medical study, comprising:

- a database component operative to maintain a medical practice (e.g. hospital) database component and their corresponding plurality of specialties (see

paragraph 5), and a clinical studies database component and their corresponding plurality of medical studies (see paragraph 24);

- a communications component to alert said medical practices (e.g. hospital) to said medical studies and receive changes to said databases (see paragraph 13); and a
- processor programmed to: update said database components (see paragraph 23);
- periodically match compatible medical information and medical studies (see paragraphs 13 and 14); and
- generate reports to matched medical practices in said medical practice database (see paragraph 23).

Baldwin teaches the features of claim 1 as explained above. It is respectfully submitted that a hospital is a location for the practice of medicine. Baldwin does not explicitly disclose matching medical specialties of medical practices with compatible medical studies. However, Veritas teaches matching medical specialties of medical practices (i.e. physicians) with compatible medical studies (see paragraphs 3 and 4). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this matching feature into the system described by Baldwin. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of enhancing the “fuzzy matching” technique disclosed by Baldwin).

As per claim 2, Baldwin and Veritas in combination disclose the system of claim 1 as explained in the rejection of claim 1. Baldwin further discloses said database component operative to maintain a patient database component identifying patients associated with each said medical practice (i.e. physician) in said medical practice database component (see paragraphs 12 and 23); said processor programmed to: update said patient database component with data supplied by said communications component (see paragraph 23); and generate reports to said matched medical practices to include a listing of prospective patients (see paragraphs 13, 14, and 23).

As per claim 3, Baldwin in view of Veritas disclose the system of claim 1 as described above. Baldwin further discloses a searching component for searching said clinical studies database (see paragraph 18); wherein said searching component is adaptable to receive queries from said medical practices via said searching components (see paragraphs 12-14).

Claims 8-10 and 16 contain substantially similar computerized method limitations to the system limitations recited in claims 1-3 and, as such, are rejected for similar reasons as given above.

5. Claim 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, **System makes it easier to link patients to clinical trials** (hereinafter Baldwin) in view of Angiogenesis Weekly, **Clinical Trials; Comprehensive Online**

Resource Launched (hereinafter Veritas) and further in view of Knight, (U.S. Patent Application No. 2002/0099570.)

As per claim 15, Baldwin and Veritas in combination disclose the method of claim 8 as described in the rejection of claim 8. Baldwin further discloses posting a for listing each said medical study in said clinical studies database (see paragraph 24). Baldwin does not explicitly disclose receiving queries from prospective patients via said posting component. However, Knight teaches a clinical trial recruitment system that includes a component for receiving queries from prospective patients (see paragraph 52). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this feature into the system described by Baldwin. One of ordinary skill in the art would have been motivated to include this feature to provide stronger, more accurate matches of clinical trials to specific patients.

6. Claims 4-6 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, **System makes it easier to link patients to clinical trials** (hereinafter Baldwin) in view of Angiogenesis Weekly, **Clinical Trials; Comprehensive Online Resource Launched** (hereinafter Veritasr) and further in view of Kraftson et al., (U.S. Patent No. 6,151,581)

As per claim 4, Baldwin and Veritas in combination teach the system of claim 2 as described in the rejection of claim 2. Baldwin does not explicitly teach maintaining a fee database component identifying fees associated with procedures performed by

medical specialties; said processor programmed to calculate a total fee to be paid to each said medical practice participating in each said medical study utilizing said fee database component.

Kraftson teaches such fee calculation features (see column 5, lines 7-22, in particular, "practice management/costs data," and column 13, lines 52-56). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this feature into the system described by Baldwin. As suggested by Kraftson one of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of better managing physician costs (see column 5, lines 59-62).

As per claim 5, Baldwin in view of Veritas and Kraftson teach the system of claim 4 as described in the rejection of claim 4. Baldwin does not explicitly teach a fee database component operative to maintain a doctor's fee database component identifying fees associated with doctor's procedures as part of said medical studies and an ancillary fee database component identifying fees associated with miscellaneous charges associated with said medical studies; said processor programmed to calculate said total fee from said doctor's fee database component and said ancillary fee database component.

Kraftson teaches maintaining such a fee database component (see column 10, lines 40-54). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this feature into the system

described by Baldwin. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of better managing physician costs (see column 5, lines 59-62).

As per claim 6, Baldwin in view of Veritas and Kraftson teach the system of claim 5 as described in the rejection of claim 5. Baldwin does not explicitly disclose generating a billing statement based upon said total fee and a number of patients actually enrolled in one of said plurality of medical studies.

Kraftson teaches such billing features (see column 10, lines 40-54). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this feature into the system described by Baldwin. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of better managing physician costs (see column 5, lines 59-62).

Claims 11-14 contain substantially similar computerized method limitations to the system limitations recited in claims 4-6 and, as such, are rejected for similar reasons as given above.

7. Claims 7 and 17 are under 35 U.S.C. 103(a) as being unpatentable over Baldwin in view of Veritas and in further view of Briegs et al (US 7,054,823).

As per claims 7 and 17, Baldwin and Veritas in combination disclose the limitations of claims 2 and 9 as explained in the rejections of claims 2 and 9, but do not

expressly disclose that the processor is programmed to generate a metric of completed components of the medical study or timeline for completion of the study.

Briegs discloses a system and method wherein timelines and deadlines for study milestones are generated. (col. 9, lines 32-48) It would have been obvious at the time of the Applicant's invention to further modify the teachings of Baldwin and Veritas in combination with the teachings of Briegs to generate timelines and deadlines for the study. As suggested by Briegs, one would have been motivated to include this feature to ensure that the study remains coordinated and well-organized. (col. 1, lines 35-50)

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./
Examiner, Art Unit 3626

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626